UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA	:	Hon. Anne E. Thompson
	:	
v.	:	
	:	
ALBERT POET	:	Criminal No. 06-643

GOVERNMENT'S MEMORANDUM OF LAW ON ANTICIPATED TRIAL ISSUES

CHRISTOPHER J. CHRISTIE
United States Attorney
970 Broad Street
Newark, New Jersey 07102
(973) 645-2700

On the Memorandum:

EUGENIA A. P. COWLES
JAMES P. LYNCH
Assistant U.S. Attorneys
401 East State Street, Room 430
Trenton, NJ 08608

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PRELIMINARY STATEMENT

The United States respectfully submits this Memorandum which addresses certain evidentiary issues that the Government anticipates might arise at trial, including: (i) presentation of evidence or argument regarding the alleged quality of the TRI toxin; (ii) presentation of evidence or argument related to the validity of Allergan's trademark for BOTOX®; and (iii) presentation of evidence or argument related to the purchase and use of the TRI toxin by other doctors.

The United States requests leave to supplement this Memorandum as other issues may arise during trial.

I. ARGUMENT OR EVIDENCE FROM THE DEFENSE REGARDING THE PURPORTED QUALITY OF THE TRI TOXIN IS IRRELEVANT AND SHOULD BE EXCLUDED TO PRECLUDE JURY NULLIFICATION

From pre-trial discussions and discovery, it appears that Dr. Poet plans to present evidence regarding the quality of the TRI toxin that he substituted for BOTOX® as alleged in the Indictment. For instance, on February 14, 2007, the defense sent a letter to the government disclosing its intent to call Dr. Garry S. Brody to testify "on the use of non-FDA approved substances in the practice of medicine." Logically, the government must assume that the defense intends to use evidence that non-FDA approved substances are used in the practice of medicine to suggest that Dr. Poet's use of the TRI toxin was appropriate. Likewise, the defense has requested an unredacted document from the Food and Drug Administration apparently indicating that in 2001, Allergan, the maker of BOTOX®, purchased Botulinum Toxin Type A from the same laboratory that supplied TRI in 2004. Evidence of a common source of the toxin would presumably support a defense that the TRI toxin was "like" BOTOX®, and again imply that Dr. Poet's use of the toxin was somehow appropriate. Similarly, affidavits submitted with the defense's omnibus motion suggest that the defense may attempt to elicit testimony from patients of Dr. Poet that they had good results from the treatments later identified as involving the TRI toxin, or, as the defense repeatedly emphasized in the press at the time of the initial appearance, that no one was harmed by the use of the TRI toxin in this case. See Schweiger, Tristan J., "FDA: Stafford doctor used unapproved form of Botox," Asbury Park Press, August 27, 2006; Mueller, Mark, "Doctor is accused of drug substitution, allegedly used dangerous Botox fake," The Star Ledger, August 26, 2006.

During the motions hearing in this case and through correspondence, the defense has repeatedly requested information from the government regarding allegations of harm to patients resulting from treatments with the TRI toxin. As is clear from the Indictment, the United States has not alleged physical harm to any patients because of the use of the TRI toxin. Further, because Dr. Poet concealed his use of the TRI toxin by avoiding reference to it in his patient files, it would be extremely difficult to establish that any given reaction resulted from the TRI toxin. Most importantly, fraud, not physical harm, is the issue in this case.[1] Just as the defense should not present irrelevant evidence about benefit from the TRI toxin the government does not intend to affirmatively present evidence of harm from it.

Arguments suggesting that the TRI toxin was a "good" option for patient treatment are irrelevant to the case at hand. The TRI toxin was not BOTOX®. By providing it to his patients in place of BOTOX®, without disclosing that the patients were not receiving the FDA-approved drug advertised in his materials and discussed in his office and were instead receiving an unapproved toxin marked "Not for Human Use" and "For Research Purposes Only," Poet defrauded his patients. BOTOX® was and is the only drug of its kind approved by the FDA for the treatment of humans. The comparative quality of BOTOX® and the unapproved TRI toxin is irrelevant to the case at hand. As charged in the Indictment, the issue for the jury is simply whether or not Dr. Poet provided the unapproved TRI toxin while representing to his patients that he was providing the FDA-approved drug BOTOX®. Evidence of TRI's "quality" can only be intended to distract the jury from the relevant issues or to convince the jury to acquit the

[1]As indicated in the Indictment, although Dr. Poet charged patients the same price whether they received the requested BOTOX® or the substitute TRI substance, the TRI substance was substantially cheaper for Dr. Poet to purchase.

defendant on inappropriate grounds. Such evidence, therefore, should be excluded.

Federal courts have been vigilant in prohibiting the defense of jury nullification in any of its many forms. See United States v. Bruce, 109 F.3d 323, 327 (7th Cir.), cert. denied, 522 U.S. 838 (1997). One court has stated:

> A jury has no more "right" to find a "guilty" defendant "not guilty" than it has to find a "not guilty" defendant "guilty," and the fact that the former cannot be corrected by a court, while the latter can be, does not create a right out of a power to misapply the law. Such verdicts are lawless, a denial of due process and constitute an exercise of erroneously seized power.

United States v. Washington, 705 F.2d 489, 494 (D.C. Cir. 1983). Simply put, there is no place in the federal court system for jury nullification. See United States v. Thomas, 116 F.3d 606, 615 (2d Cir. 1997).

Because the jury enjoys no right to nullify criminal laws, the defendant has no consequent right to (1) adduce evidence probative of the irrelevant issue of nullification and which is not probative of any legitimate defense; (2) argue nullification to the jury; or (3) have the Court give a nullification instruction to the jury. United States v. Funches, 135 F.3d 1405, 1409 (11th Cir.), cert. denied, 524 U.S. 962 (1998). Federal courts absolutely bar defense examination on nullification including any evidence the sole purpose of which is to encourage the finder of fact to disregard the law. See United States v. Lucero, 895 F. Supp. 1421, 1426 (D. Kan. 1995).

Courts are so concerned about their responsibilities to protect nullification that they regularly have granted the Government's *in limine* motions to prohibit defense attempts (1) to adduce evidence regarding, and (2) to argue, nullification. For instance, in United States v. Andreas, a criminal antitrust price-fixing matter, the Government moved to preclude the

defendants from adducing evidence and arguing, among other things, that their conduct actually was good for the market. The Court precluded the argument, explaining that, "[a]s a matter of law, the defendants are prohibited from raising a jury nullification argument to the jury." 23 F. Supp. 2d 835, 852 (N. D. Ill. 1998).

The Court should not permit the defense to stray from material issues and present jury nullification arguments. Accordingly, the United States requests that this Court issue an order preventing the defense from adducing evidence or making arguments regarding jury nullification.

II. CONSISTENT WITH THIS COURT'S PRIOR RULING, ARGUMENT OR EVIDENCE REGARDING TRADEMARK ISSUES IS IRRELEVANT AND SHOULD BE EXCLUDED TO AVOID WASTE OF TIME AND JUROR CONFUSION

In a second February 14, 2007, letter, defendant Albert Poet informed the government of his intent to call Professor Jeffrey Samuels of the University of Akron School of Law to testify that the term "Botox" is generic and, presumably, that it cannot therefore be used to identify a single, specific drug. The defense initially presented this line of argument in his omnibus motion dated January 16, 2007, arguing that the Indictment should be dismissed because the term "Botox" is generic as a matter of law. The Court summarily denied that motion.

Any argument that the term "Botox" is generic and/or that Allergan's trademark on BOTOX® is therefore invalid is irrelevant to the present case. Such an argument, extended to the facts at hand, would likely maintain that if the term "Botox" were generic, then Dr. Poet could not have defrauded his patients by injecting them with the TRI toxin when they believed they were receiving BOTOX®. This argument, however, misconstrues the allegations in the Indictment. This case is about fraud. As the government will show at trial, BOTOX® is the

only FDA-approved Botulinum Toxin Type A marketed in the United States for use in humans. Whether or not the term "Botox" is trademarked, patients seeking treatment with "Botox" are clearly requesting the one and only product with that name currently available for sale in the U.S. Again, the issue in this case is one of fraud, not of trademark law.[2] Importantly, the evidence shows and Dr. Poet admitted in his proffer that he did not tell his patients he had two products from which they could choose— one FDA approved, one not. Instead, he actively concealed the existence of the second product, even failing to record in patient files which drug had been injected.

Under Federal Rule of Evidence 401, "relevant evidence" is defined as "evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Under Federal Rule of Evidence 403, even relevant evidence is subject to a balancing test pitting potential value to the case against the court's concerns about wasted time and jury confusion. As the Third Circuit has explained, particularly in cases in which the jury will hear "esoteric" information, such as the evidence anticipated here regarding the nature and approval for use in humans of Botulinum Toxin Type A, "the district court must be permitted to keep the jury's attention focused on the issues by excluding irrelevant and even misleading evidence." See United States

[2]Consider the questions pertinent to each scenario: The fraud case asks, "Did Dr. Poet deceive his patients by advertising and discussing 'Botox' but providing them with an unapproved toxin?" The likely trademark case, by contrast would ask, "If Dr. Poet wanted to market his own form of Botulinum Toxin Type A, could he call it 'Botox?'" Notably, the facts in this case suggest Dr. Poet did not want to market his own form of Botulinum Toxin Type A. Instead, he worked to conceal the existence of a second form of toxin, repeatedly listing "BOTOX" in his advertisements, on his website, on his consent forms, and even on brochures in his office, and failing to mention the alternative treatment option to his patients.

v. Sain, 141 F.3d 463, 475-76 (3d Cir. 1998). Thus, where evidence does not negate participation in the alleged events or form the basis for any recognized defenses to the charged crimes, it properly may be excluded. See, e.g., United States v. Romano, 849 F.2d 812, 816 n.7 (3d Cir. 1988).

Evidence pertaining to the validity of Allergan's trademark for BOTOX® does not make any fact of consequence more or less probable. Even if the evidence were of some marginal relevance, the trademark issue risks an enormous waste of time and substantial confusion of issues for exceedingly limited evidentiary value. The Court should therefore exclude any evidence or argument pertaining to trademark law.

III. "OTHER DOCTOR" EVIDENCE

It is anticipated that the defense will attempt to advance evidence regarding the purchases and potentially the use of the TRI toxin by other doctors. If such evidence is used to suggest that the government has improperly targeted Dr. Poet for prosecution, it should be excluded. Additionally, such evidence is irrelevant to the issues in this case, namely whether Dr. Albert Poet knowingly defrauded his patients by substituting the unapproved, cheaper TRI toxin in place of the FDA-approved, and more expensive, drug BOTOX®. Further, to the extent the defense seeks to present the evidence by not calling Chad Livdahl, the maker of the TRI toxin, nor the doctors who made the purchases, but instead the FDA agents who interviewed the doctors, the evidence is clearly inadmissible hearsay.

A. ARGUMENT OR EVIDENCE SUGGESTING SELECTIVE PROSECUTION SHOULD BE EXCLUDED

The United States moves *in limine* to preclude Poet from presenting evidence or arguments to the jury regarding claims of selective prosecution. As the defendant is well aware,

the investigation of this case arose out of a broader, national investigation of the TRI toxin used by Dr. Poet. It is anticipated that the defendant will suggest, either through questions or argument, that the United States has engaged in selective or vindictive prosecution because it has "targeted" the defendant in this case while not charging all other doctors who ordered the unapproved toxin from TRI. The defendant's anticipated argument is totally inappropriate to advance to a jury. Accordingly, the Court should bar the defense from advancing this type of argument at any time and in any manner.

The argument regarding the prosecution or non-prosecution of other doctors is irrelevant to the charged crime. Moreover, such a defense claim is one of selective prosecution. Any attempt to advance a selective prosecution claim to the jury has been foreclosed by the United States Court of Appeals for the Third Circuit in United States v. Berrigan, 482 F.2d 171 (3d Cir. 1973). In that case, Father Philip Berrigan and others were successfully prosecuted for smuggling letters in and out of a federal prison without the warden's consent. The letters concerned a conspiracy to kidnap Henry Kissinger and otherwise disrupt the functioning of the federal government and the Selective Service System. At their trial, the defendants argued that "the prosecution . . . was conducted for political reasons, because of defendants' efforts to end the use of United States military forces in Southeast Asia and for personal reasons to vindicate the reputation of" the former FBI Director, J. Edgar Hoover. Id. at 173. When the defendants sought to introduce evidence of discriminatory prosecution to the jury, the trial court refused. The Third Circuit affirmed, explaining: "The question of discriminatory prosecution relates not to the guilt or innocence of appellants, but rather addresses itself to a constitutional defect in the institution of the prosecution." Id. at 175. Therefore, the appellate court agreed with the trial

court that such a matter was for the trial court, and not the jury, to decide pre-, or perhaps, post-trial. Id. at 174-75, 182.

Berrigan dooms any defense attempt to comment on any alleged motive for prosecution. Under Berrigan, such arguments simply are not for the jury to hear, much less decide. Other district courts have ruled similarly on the issue of presenting a claim of selective prosecution to a jury. See United States v. Andreas, 23 F. Supp. 2d 835, 854 (N.D. Ill. 1998); United States v. Conley, 859 F. Supp. 909, 936-37 (W.D. Pa. 1994); see also United States v. Napper, 553 F. Supp. 231, 232 (E.D.N.Y. 1982) ("The defendant does not have the right to present a selective prosecution claim to a jury.").

Significantly, the defendants could not even make out a *prima facie* claim of selective prosecution to the Court. To do so, they must establish: 1) that they were singled out for prosecution while others similarly situated were not prosecuted; and 2) that the selective decision to prosecute them was based on impermissible grounds of discrimination on the basis of race, religion, ethnicity, etc., or for exercising a constitutionally protected right. See United States v. Bell, 113 F.3d 1345, 1351-52 n.6 (3d Cir.), cert. denied, 522 U.S. 984 (1997); Jarrett v. United States, 822 F.2d 1438, 1443 (7th Cir. 1987); see also Oyler v. Boles, 368 U.S. 448, 456 (1962). There is no evidence that the prosecution was motivated by impermissible discrimination or in retaliation for exercising a constitutionally protected right. Absent such evidence, decisions about whom, whether and when to prosecute are the function of the executive branch of government and are properly left to the prosecutor.

For these reasons, the United States asks the Court to preclude any argument, questioning, or evidence, suggesting selective prosecution in this case.

B. EVIDENCE REGARDING PURCHASES BY OTHER DOCTORS IS IRRELEVANT

From late 2003 through the end of 2004, TRI sold its unapproved Botulinum Toxin Type A to doctors throughout the country. Through the discovery process, it appears that the defense may plan to present evidence pertaining to the interactions of these other doctors with Chad Livdahl, the head of TRI, as well as the doctors' purchase and use of the TRI substance. This evidence is irrelevant to the matter at hand.

As Rule 401 explains, evidence is relevant if it makes a fact of consequence more or less probable. At issue in this case are facts pertaining to Dr. Poet's purchase, use, and concealment of the identity of the TRI toxin. Whether or not other doctors decided to pursue the use of the TRI substance in their practices has no bearing on whether, or how, Dr. Poet used the substance on his patients. Further, whether or not other doctors intended to defraud their patients by using the substance sheds no light on whether or not this defendant substituted the TRI toxin for BOTOX® in the treatment of unknowing patients with an intent to defraud. Thus, evidence of the purchase and use of the TRI toxin by other doctors should be excluded as irrelevant to this case.

C. EVIDENCE FROM FDA SPECIAL AGENTS REGARDING STATEMENTS MADE TO THEM BY DOCTORS RECOUNTING STATEMENTS MADE BY CHAD LIVDAHL IS INADMISSIBLE HEARSAY

On February 14, 2007, defense counsel sent a letter to the FDA enclosing subpoenas for twenty-two (22) present and former FDA agents, a copy of which was provided to the government. In the accompanying 21 C.F.R. § 20.1(c) submission, defense counsel explains

the testimony of these agents as follows:

> 5. . . . [E]ach of the Special Agents conducted interviews with physicians and/or others concerning the purchase of Toxin Research International, Inc.'s botulinum toxin type A.
>
> 6. In addition, Special Agent Susan Leeds was the primary investigator, and she was present at the execution of a search warrant on the premises of Toxin Research International. Further, Special Agent Leeds has specific information concerning the conduct of, and statements by Chad Livdahl.
>
> 7. Further, Consumer Safety Officer Randall Johnson was also intimately involved in the investigation of Chad Livdahl and Toxin Research International, Inc., and he interviewed both Chad Livdahl and Zahra Karim prior to any action being brought by the FDA.
>
> 8. The testimony of these employees is necessary because, among other things, certain statements that Chad Livdahl made to these individuals are not otherwise obtainable by the defense.

Cert. of William J. Hughes, Jr., 2/14/07, ¶¶ 5-8. To the extent the defense intends to call these agents to testify to statements Chad Livdahl purportedly made to doctors interviewed by the agents, the statements are inadmissible double hearsay. See F.R.E. 801-804. It should be noted that if the defense desires to introduce relevant evidence from Livdahl, as the defense is well aware, the United States has arranged for Chad Livdahl to be transferred to New Jersey from the Federal Correctional Institute in Safford, AZ, so that he is available to be called by either party as a witness at trial. If the ultimate goal of the witnesses is to provide information about

Livdahl's

representations to Dr. Poet, to the extent that such representations may be relevant, Livdahl himself is available for testimony.

For these reasons, since the testimony of the subpoenaed witnesses is clearly inadmissible, the Court should so rule before trial to avoid unnecessary expense on the part of the defense in bringing the witnesses to New Jersey and unnecessary inconvenience and burden on the subpoenaed agents.

IV. CONCLUSION

For the reasons articulated above, the Court should exclude evidence of the quality of the TRI toxin and the validity or invalidity of Allergan's trademark on BOTOX® should these issues be raised at trial. Further, evidence or argument relating to purchases of the TRI toxin by other doctors should be excluded as improperly alleging selective prosecution or as irrelevant to the case at hand. Finally, if, as appears clear from the submission to the FDA, the testimony of the subpoenaed agents is inadmissible double hearsay, the Court should so rule in advance of trial to preclude unnecessary expense and travel.

Respectfully submitted,

CHRISTOPHER J. CHRISTIE
United States Attorney
/s Eugenia A. P. Cowles

By: EUGENIA A. P. COWLES
Assistant U.S. Attorney

JAMES P. LYNCH

Assistant U. S. Attorney

Dated: March 1, 2007
Trenton, New Jersey

CERTIFICATE OF SERVICE

I, Eugenia A. P. Cowles, Assistant United States Attorney, do hereby certify that on this date, I served the foregoing Government's Memorandum of Law on Anticipated Trial Issues as follows:

VIA FACSIMILE AND FIRST CLASS MAIL

Mr. William J. Hughes, Jr.
Cooper Levenson Law Offices
1125 Atlantic Avenue, 3rd Floor
Atlantic City, NJ 08401
(609) 344-0939

Mr. Jerome A. Ballarotto, Esq.
143 Whitehorse Avenue
Trenton, NJ 08610
(609) 581-9509

Dated: March 1, 2007

/s Eugenia A. P. Cowles
_____
Eugenia A. P. Cowles
Assistant United States Attorney